

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/019,316	01/09/2002	Graziano CastaldI	108907-00024	907-00024 7392	
4372 7590 03/19/2003 ARENT FOX KINTNER PLOTKIN & KAHN 1050 CONNECTICUT AVENUE, N.W. SUITE 400			EXAMINER		
			SAEED, KAMAL A		
	ON, DC 20036		ART UNIT	PAPER NUMBER	
			1626 DATE MAILED: 03/19/2003	7	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	n No.	Applicant(s)				
Office Action Summary		10/019,316	,	CASTALDI ET AL.				
		Examiner		Art Unit				
		Kamal A Sa		1626				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address								
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM								
THE MA - Extensior after SIX - If the peri - If NO peri - Failure to	TENED STATUTORY PERIOD FOR REP ILING DATE OF THIS COMMUNICATION as of time may be available under the provisions of 37 CFR 1 (6) MONTHS from the mailing date of this communication. od for reply specified above is less than thirty (30) days, a re iod for reply is specified above, the maximum statutory perio reply within the set or extended period for reply will, by state received by the Office later than three months after the mail attent term adjustment. See 37 CFR 1.704(b).	I. 1.136(a). In no ever eply within the statut d will apply and will the cause the appli	nt, however, may a reply be time ory minimum of thirty (30) days expire SIX (6) MONTHS from cation to become ABANDONE	ely filed will be considered timely. the mailing date of this communication. (35 U.S.C. § 133).				
	esponsive to communication(s) filed on <u>08</u>	8 April 2002 .						
,—-	•	This action is i	non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
C Disposition		ei Ex parte Qu	ayle, 1999 O.D. 11, 4	00 0.0. 210.				
•	4)⊠ Claim(s) <u>1-7</u> is/are pending in the application.							
4a)	4a) Of the above claim(s) is/are withdrawn from consideration.							
5) <u></u> Cl	5) Claim(s) is/are allowed.							
6)⊠ CI	6)⊠ Claim(s) <u>1,4 and 5</u> is/are rejected.							
•	aim(s) <u>2,3,6 and 7</u> is/are objected to.							
	aim(s) are subject to restriction and	l/or election re	equirement.					
Application		nor						
•	e specification is objected to by the Exami e drawing(s) filed on is/are: a)□ ac		objected to by the Exa	miner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.								
If approved, corrected drawings are required in reply to this Office action.								
12) The oath or declaration is objected to by the Examiner.								
Priority und	der 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a)⊠	All b)☐ Some * c)☐ None of:							
1.	1. Certified copies of the priority documents have been received.							
2.	2. Certified copies of the priority documents have been received in Application No							
3. ☑ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.								
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).								
a) The translation of the foreign language provisional application has been received.								
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.								
Attachment(s			4) Interview Summar	y (PTO-413) Paper No(s)				
2) Notice of	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) tion Disclosure Statement(s) (PTO-1449) Paper No(s	s) <u>6</u> .		Patent Application (PTO-152)				

Page 2

Application/Control Number: 10/019,316

Art Unit: 1626

DETAILED ACTION

Claims 1-7 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

- 1. the nature of the invention,
- 2. the state of the prior art,
- 3. the predictability or lack thereof in the art,
- 4. the amount of direction or guidance present,
- 5. the presence or absence of working examples,
- 6. the breadth of the claims,
- 7. the quantity of experimentation needed, and
- 8. the level of the skill in the art.

A greater amount of evidentiary support is needed in order to fully satisfy the requirement of 35 USC 112, first paragraph, regarding sufficient guidance on "how to use" the invention. In the instant case, in claim 1, recites "R₃ is methyl, ethylor the residue of a saturated heterocyclic ring having 5 or 6 atoms". What is "residue of a saturated heterocyclic ring having 5 or atoms"? There is no support in the specification regarding this

Art Unit: 1626

language. A chemical process or synthesis is first classified by classifying the chemical compound which is prepared end product and then the process is or synthesis is searched based on the classification of the specific chemical compound. The specification does not give any guidance how to prepare (nitroxymethyl)phenyl esters compounds having a **residue of a saturated heterocyclic ring having 5 or 6 atoms**. Applicants' examples are directed to process of preparing nitroxymethylphenyl ester of 2-acetoxybenzoic acid (See page 10 and 11, examples 4, 5, and 6). However, the claim is so broad that a skilled artisan would be faced with unlimited number of nitroxymethylphenyl ester compounds that have unlimited number of substituents and it would require undue experimentation to make or use the invention. A suggestion to obviate the rejection would be to delete "......or the residue of a saturated heterocyclic ring having 5 or 6 atoms" from claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "the residue of a saturated heterocyclic ring having 5 or 6 atoms" renders claim 1, indefinite. As stated above, what is the residue of a saturated heterocyclic ring having 5 or 6 atoms"? The term residue is vague and unclear. It is suggested to delete the language "residue of the residue of a saturated heterocyclic ring having 5 or 6 atoms"

Art Unit: 1626

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 1, line recites the broad recitation "ortho, meta or para position", and the claim also recites "preferably the position is the meta one" which is the narrower statement of the range/limitation. It is suggested to delete the term "preferably" and write the narrower range as an independent claim.

Claim 1, line 4, recites the broad recitation " R_1 is the OCOR $_3$ group" and in line 12, the claim also recites "preferably R_1 is acetoxy" which is the narrower statement of the range/limitation. It is suggested to delete the term "preferably" and write the narrower range as an independent claim.

Claim 1, line 8, recites the broad recitation "R₂ is hydrogen, halogenmono- or di alkylamino" and in line 12 and 13, the claim also recites "preferably R₂ is hydrogen" which is

Art Unit: 1626

the narrower statement of the range/limitation. It is suggested to delete the term "preferably" and write the narrower range as an independent claim.

Claim 4, lines 3 and 4, recites the broad recitation "acid halide (IA) in the range between 1 and 2" and in line 5, the claim also recites "preferably between 1.2 and 1.5" which is the narrower statement of the range/limitation. It is suggested to delete the term "preferably" and write the narrower range as an independent claim.

Claim 5, lines 3 and 4, recites the broad recitation "nitric acid in the ratio between 1 and 6" and in lines 5 and 6, the claim also recites "preferably between 1 and 3" which is the narrower statement of the range/limitation. It is suggested to delete the term "preferably" and write the narrower range as an independent claims.

Claim Objections

Claims 2, 3, 6 and 7 are objected to as being dependant on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal Saeed whose telephone number is (703) 308-4592. The examiner can normally be reached on Monday-Friday from 8:00 AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308 4537. The unofficial fax phone for this group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right)

Art Unit: 1626

"Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application.

This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signiture, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Kamal Saeed, Ph.D., March 17, 2003 Celia C. Chang, Ph.D., Primary Patent Examiner Art Unit 1626, Group 1620 Technology Center 1

ush K. M Kore For: